



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

*In re* application of: )  
S. Kossida *et al.* ) Group Art Unit: 1653  
Serial No.: 10/631,958 ) Examiner: M. Monshipouri  
Filed: December 19, 2003 ) Atty. Docket: 004974.00951

For: REGULATION OF HUMAN CERAMIDE KINASE

**APPLICATION FOR PATENT**  
**TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)**

Mail Stop Issue Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants hereby request reconsideration of the patent term adjustment of the above identified application.

The fee of \$200.00 as required by 37 C.F.R. § 1.18(e) is enclosed herewith. However, if the Patent Office determines that additional fees are due, the Commissioner is hereby authorized and directed to debit our Deposit Account No. 19-0733.

12/29/2005 MBEYENE2 00000031 190733 10631958  
03 FC:1455 200.00 DA

### STATEMENT OF FACTS

1. Applicants filed application serial number 10/631,958 on August 1, 2003. See Exhibit 1 which is a copy of the postcard receipt filed with the application.
2. The Patent Office mailed a first action under 35 U.S.C. § 132, a restriction requirement, on August 2, 2005. See Exhibit 2, which is a copy of the restriction requirement mailed August 2, 2005.
3. Fourteen months and three hundred five days elapsed between the filing date of the application and the mailing of a first action under 35 U.S.C. § 132.
4. The Patent Office acknowledges that applicants would be entitled to one hundred sixty four days of extension for the delayed first action under 35 U.S.C. § 132. However, it eliminates one hundred forty one days of the patent term adjustment because it alleges that the application is only entitled to a filing date of December 19, 2003. See Exhibit 3, which is a printout of the Patent Term Adjustment for the application. Note the “Filing or 371(e) date” is indicated as being 12-19-2003.
5. The Patent Office alleges that the filing date of the application is December 19, 2003 because a Notice to Missing Parts mailed October 22, 2003 indicated that the application as filed lacked Figures 1 and 2, and therefore did not meet the requirements of 37 C.F.R. § 1.53(b) or (c). See Exhibit 4, which is a copy of the Notice to File Missing Parts mailed October 22, 2003. The last bullet point on page 1 of the Notice indicates that Figures 1 and 2 were omitted from the application.

6. To correct the filing date assigned to the application, Applicants filed a petition under 37 C.F.R. § 1.182 on September 17, 2004. See Exhibit 5, which is a copy of applicants' petition and a date stamped postcard indicating receipt of applicants' petition.
7. The Patent Office granted applicants' petition. See Exhibit 6. See the last line of ¶ 4, which states, "Accordingly, the application, as filed, was entitled to the filing date of August 1, 2003."
8. The application is entitled to a filing date of August 1, 2003.
9. The 164-day delay printed on the Patent Office's Patent Term Adjustment calculation is erroneous.
10. No other applicant delay is indicated on the Patent Office's Patent Term Adjustment records.
11. Applicants engaged in reasonable efforts to conclude processing or examination of the application as set forth in 37 C.F.R. § 1.704.
12. No terminal disclaimer was filed in the subject application.
13. Applicants are entitled to three hundred five days of patent term adjustment for the Patent Office's delay in mailing of a first action under 35 U.S.C. § 132 after the filing of the application.

**POINT TO BE REVIEWED**

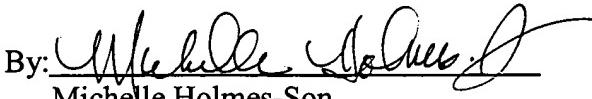
The point to be reviewed is whether the above-mentioned application should receive a patent term adjustment of three hundred five days.

ACTION REQUESTED

Applicants request that this application under 37 CFR § 1.705(b) be accepted and that three hundred five days be added to the term of the patent that issues from this application.

Respectfully submitted,

Date: December 27, 2005

By:   
Michelle Holmes-Son  
Registration No. 47,660

Banner & Witcoff, Ltd.  
1001 G Street, NW  
Washington, DC 20001  
202-824-3000

List of Exhibits

- Exhibit 1. Copy of postcard receipt indicating application filing date of August 1, 2003.
- Exhibit 2. Copy of Restriction Requirement mailed August 2, 2005.
- Exhibit 3. Printout of Patent Term Adjustment history from PAIR.
- Exhibit 4. Copy of the Notice to File Missing Parts mailed October 22, 2003.
- Exhibit 5. Copy of applicants' petition to accord the application a filing date of August 1, 2003 and a date stamped postcard indicating receipt of applicants' petition.
- Exhibit 6. Copy of Patent Office's decision to grant applicants' petition to accord the application a filing date of August 1 2003.

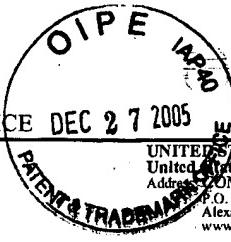
## **EXHIBIT 1**



PATENT  DESIGN B&W Ref. 4974.951 Date 8/1/03  
 HAND CARRY Group/Section tha  
 Serial/Patent No 102 Bldg. LMH 1 met  
 Inventor Kosanda + ENCINAS Rm. 26  
 Client Bayer AG  
 Title Regulation of Human Ceramide Kinase  
  
 The following has been received in the U.S. Patent and Trademark Office on the date stamped hereon:  
4974.951 total pp Spec., including: # of Claims 65  
 # of independent claims 21;  Abstract  
 Drawing 2 Formal  Informal  
 # of distinct sheets 8 Figs. 1-8  
 Declaration/Power of Attorney:  Executed  Unexecuted  
 Assignment w/PTO Cover Sheet  
 DS w/PTO 149  References  w/free  
 Preliminary Amendment  
 Priority Claim (Foreign or U.S. Provisional) B&W # \_\_\_\_\_  
  
 Country \_\_\_\_\_ Appl. # \_\_\_\_\_ Date \_\_\_\_\_  
 w/Foreign Priority Document(s)  
 Application 102  Continuation 4974.951  Divisional  
 Parent Ser. No. 01/169211 A W/ 4974.951  
 U.S. Provisional 102  S-60 Claims, Cover Sheet  
 Response to Missing Parts/Requirements ADS  
 Response to Notice to File Corrected Appl. Papers ADS  
 Request for Expedited Foreign Filing License  
 Request for Corrected  Filing Receipt  
 Response to Restriction/Election Requirement ADS  
 Assignment  
  
 Atty/Sec. LMH 1 met  
 Client Bayer AG  
  
 Sequence Listing:  Diskette  Paper 12 pages  
 Amendment  Response: OA do  
 Petition for Extension of Time and 01/05  
 CPA  RCE  w/Ext. of Time: OA do  
 Request for Approval of Drawing Changes  
 Notice of Appeal & Fee  
 Brief:  Appeal & Fee  Reply  
 Request for Oral Hearing  
 Issue Fee  Advance Patent Copies (# desired)  
 Notice of Allowance ADS  
 Amendment under 37 CFR 1.312  
 Request for Certificate of Correction  
 Transmittal  Fee Transmittal w/Auth. to Charge Deposit Acc.  
 Certificate of Mailing  
 Check \_\_\_\_\_ for \$ \_\_\_\_\_  
  
 REC'D. ADS  
 RECEIVED AND RECEIVED AND  
 Sequence listing from 01/05 ADS  
 Another Application  
 w/ statement



## UNITED STATES PATENT AND TRADEMARK OFFICE



## EXHIBIT 2

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/631,958      | 12/19/2003  | Sophia Kossida       | 004974.00951        | 3681             |

22907 7590 08/02/2005

BANNER & WITCOFF  
1001 G STREET NW  
SUITE 1100  
WASHINGTON, DC 20001

RECEIVED

AUG 04 2005

BANNER WITCOFF

EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Docketed 8/4/05

Attny MHD/LMH

Please Ref 004974.00951

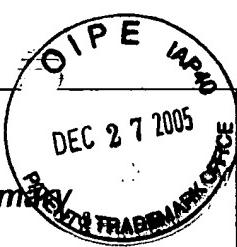
Action 1 month OA Restriction

Due Date 9/2/05

Last Day 2/2/06

By wlm

*[Handwritten signatures and initials over the bottom right of the processing information]*



## Office Action Summary

|                    |                |  |
|--------------------|----------------|--|
| Application No.    | Applicant(s)   |  |
| 10/631,958         | KOSSIDA ET AL. |  |
| Examiner           | Art Unit       |  |
| Maryam Monshipouri | 1653           |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-77 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-77 are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 
- I. Claims 1-9, 16-17, 20, 51, 53, 55-56, and 61-63, 65, drawn to DNA encoding human sphingosine kinase-like proteins (referred to as "kinases" from now on), methods of expressing said sequences, kits comprising said sequences, pharmaceutical compositions comprising said sequences, and oligonucleotides that hybridize to said sequences, classified in class 435, subclass 194.
- II. Claims 10-15 and 23, drawn to said kinases, kits and fusion proteins comprising said kinases, classified in class 435, subclass 194.
- III. Claims 18-19, drawn to methods of use of said DNA sequences in a hybridization assay, classified in class 435, subclass 6.
- IV. Claims 21-22, 49-51, 54 and 64, drawn to antibodies which bind said kinases, pharmaceutical compositions comprising said antibodies and methods of use of said antibodies, classified in class 435, subclass 7.1.
- V. Claims 24-48 and 75, 77, drawn to methods of screening for modulators of said kinases or apoptosis inducing agents, classified in class 435, subclass 15.
- VI. Claims 51-52 drawn to a pharmaceutical composition comprising ribozymes, classified in class 514, subclass 12.
- VII. Claims 57-60, drawn to methods of treatment using modulators of said kinases, classified in class 514, subclass 789.

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VIII. Claims 66-74, drawn to method of inducing apoptosis utilizing an apoptosis inducing agent, classified in class 514, subclass 12.

IX. Claims 76, drawn to apoptosis inducing agents, classification unknown.

This is because classification depends on the chemical structure of the agent and applicant has not defined the chemical structure of said agent.

The inventions are distinct, each from the other because of the following reasons:

The DNA of Group I, the polypeptides of Group II, the antibodies of Group IV, the ribozymes of Group VI and the apoptosis inducing agents of Group IX are each patentably distinct from the other because each product is directed to an unrelated chemical structure and function.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Groups I may be used for recombinant expression of said kinases which is a totally different method than methods of Groups III.

The DNA of Group I is unrelated to any of the methods of Groups V, VII and VIII because said products are neither made nor used by any of said methods.

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The polypeptides of Group II are unrelated to any of the methods of Group III, VII and VIII because said products are neither made nor used by said methods.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group II may be used for antibody preparation which is totally different method than that of Group V.

The antibodies of Group IV are unrelated to any of the methods of Group III, V, VII and VIII because said products are neither made nor used by any of said methods.

The ribozymes of Group VI are unrelated to any methods of Group III, V, VII and VIII because said products are neither made nor used by any of said methods.

The apoptosis inducing agents of Group IX are unrelated to any of the methods of Groups III, V and VII because said products are neither made nor used by any of said methods.

Inventions IX and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case UV radiation may

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be used for induction of apoptosis which is a totally different product than that of Group IX.

The methods of Groups III, V, VII and VIII are each patentably distinct from the other because each method has different steps and different end-points.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their separate classification, restriction for examination purposes as indicated is proper.

Claims 1-10, and 14-77 are generic to a **plurality of disclosed patentably distinct species** comprising SEQ ID NO:2, 10 and 11, structurally distinct enzymes. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP section 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all the criteria for patentability including the requirement of 35 U.S.C. 101, 102, 103 and 112. Until an alerted product claims is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

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commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. section 103(b)," 1184 O.G. 86(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include limitations of the product claim. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP section 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*M. Monshipouri*

Maryam Monshipouri Ph.D.

Primary Examiner

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**EXHIBIT 3****United States Patent and Trademark Office**[Home](#) | [Site Index](#) | [Search](#) | [FAQ](#) | [Glossary](#) | [Guides](#) | [Contacts](#) | [eBusiness](#) | [eBiz alerts](#) | [News](#) | [Help](#)**PATENT APPLICATION INFORMATION RETRIEVAL****Patent Term Adjustment (PTA) for publication number: 10/631,958**

|                              |            | Days                        |
|------------------------------|------------|-----------------------------|
| Filing or 371(c) Date:       | 12-19-2003 | USPTO Delay (PTO):          |
| Issue Date of Patent:        | -          | Three Years:                |
| Pre-Issue Petitions (days):  | +0         | Applicant Delay (APPL):     |
| Post-Issue Petitions (days): | +0         | Total PTA:                  |
| USPTO Adjustment (days):     | +0         | Explanation of Calculations |

**Search Options**

|                     |
|---------------------|
| Continuity Data     |
| Display References  |
| Image File Wrapper  |
| File History        |
| Publication Review  |
| Published Documents |

**Patent Term Adjustment History**

| Date       | Contents Description                            | PTO<br>(days) | APPL<br>(days) |
|------------|---|---------------|----------------|
| 09-27-2005 | Mail Notice of Allowance                        |               |                |
| 09-27-2005 | Mail Examiner's Amendment                       |               |                |
| 09-19-2005 | Notice of Allowance Data Verification Completed |               |                |
| 09-19-2005 | Examiner's Amendment Communication              |               |                |
| 09-15-2005 | Examiner Interview Summary Record (PTOL - 413)  |               |                |
| 12-19-2003 | Information Disclosure Statement considered     |               |                |
| 08-29-2005 | Date Forwarded to Examiner                      |               |                |
| 08-12-2005 | Response to Election / Restriction Filed        |               |                |
| 08-02-2005 | Mail Restriction Requirement                    | 164           |                |
| 08-01-2005 | Requirement for Restriction / Election          |               | ↑              |
| 06-28-2005 | Case Docketed to Examiner in GAU                |               | ↑              |
| 11-08-2004 | Petition Decision - Granted                     |               | ↑              |
| 09-17-2004 | Petition Entered                                |               | ↑              |
| 09-17-2004 | Workflow incoming petition IFW                  |               | ↑              |
| 08-17-2004 | IFW TSS Processing by Tech Center Complete      |               | ↑              |
| 08-17-2004 | Case Docketed to Examiner in GAU                |               | ↑              |
| 03-22-2004 | Preliminary Amendment                           |               | ↑              |
| 12-19-2003 | Information Disclosure Statement (IDS) Filed    |               | ↑              |
| 06-21-2004 | Application Return from OIPE                    |               | ↑              |
| 06-21-2004 | Application Return TO OIPE                      |               | ↑              |
| 06-21-2004 | Application Return from OIPE                    |               | ↑              |

|            |  |  |
|------------|--|--|
| 06-21-2004 | Application Is Now Complete  |  |
| 12-19-2003 | Drawing Preliminary Amendment  |  |
| 06-21-2004 | Pre-Exam Office Action Withdrawn   |  |
| 06-21-2004 | Application Return TO OIPE   |  |
| 06-21-2004 | Application Return from OIPE   |  |
| 06-21-2004 | Application Is Now Complete  |  |
| 06-21-2004 | Application Return TO OIPE   |  |
| 06-21-2004 | Application Return from OIPE   |  |
| 06-21-2004 | Application Is Now Complete  |  |
| 06-21-2004 | Application Return TO OIPE   |  |
| 06-21-2004 | Application Return from OIPE   |  |
| 06-21-2004 | Application Is Now Complete  |  |
| 06-21-2004 | Application Return TO OIPE   |  |
| 06-21-2004 | Application Return from OIPE   |  |
| 06-21-2004 | Application Is Now Complete  |  |
| 06-21-2004 | Pre-Exam Office Action Withdrawn   |  |
| 06-21-2004 | Application Return TO OIPE   |  |
| 06-16-2004 | Application Return from OIPE   |  |
| 06-17-2004 | Application Is Now Complete  |  |
| 06-16-2004 | Application Return TO OIPE   |  |
| 06-16-2004 | Application Dispatched from OIPE   |  |
| 06-16-2004 | Application Is Now Complete  |  |
| 03-22-2004 | Additional Application Filing Fees   |  |
| 03-22-2004 | A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic |  |
| 02-24-2004 | Notice Mailed--Application Incomplete--Filing Date Assigned  |  |
| 12-19-2003 | Payment of additional filing fee/Preexam   |  |



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

| APPLICATION NUMBER | FILING OR 371 (c) DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NUMBER |
|--------------------|------------------------|-----------------------|------------------------|
| 10/631,958         | 08/01/2003             | Sophia Kossida        | 004974.00951           |

22907  
 BANNER & WITCOFF  
 1001 G STREET N W  
 SUITE 1100  
 WASHINGTON, DC 20001

**CONFIRMATION NO. 3681**  
**FORMALITIES LETTER**



\*OC000000011078330\*

Date Mailed: 10/22/2003

**NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION**

**FILED UNDER 37 CFR 1.53(b)**

*Filing Date Granted*

**Items Required To Avoid Abandonment:**

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.  
*Applicant must submit \$ 770 to complete the basic filing fee for a non-small entity. If appropriate, applicant may make a written assertion of entitlement to small entity status and pay the small entity filing fee (37 CFR 1.27).*
- The oath or declaration is missing.  
*A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

The following item(s) appear to have been omitted from the application:

- Figure(s) 1 & 2 described in the specification.

I. Should applicant contend that the above-noted omitted item(s) was in fact deposited in the U.S. Patent and Trademark Office (USPTO) with the nonprovisional application papers, a copy of this Notice and a petition (and \$130.00 petition fee (37 CFR 1.17(h))) with evidence of such deposit must be filed within **TWO MONTHS** of the date of this Notice. The petition fee will be refunded if it is determined that the item(s) was received by the USPTO.

II. Should applicant desire to supply the omitted item(s) and accept the date that such omitted item(s) was filed in the USPTO as the filing date of the above-identified application, a copy of this Notice, the omitted item(s) (with a supplemental oath or declaration in compliance with 37 CFR 1.63 and 1.64 referring to such items), and a petition under 37 CFR 1.182 (with the \$130.00 petition fee (37 CFR 1.17(h))) requesting the later filing date must be filed within **TWO MONTHS** of the date of this Notice.

Applicant is advised that generally the filing fee required for an application is the filing fee in effect on the filing date accorded the application and that payment of the requisite basic filing fee on a date later than the filing date of the application requires payment of a surcharge (37 CFR 1.16(e)). To avoid processing delays and payment of a surcharge, applicant should submit any balance due for the requisite filing fee based on the later filing date being requested when submitting the omitted items(s) and the petition (and petition fee) requesting the later filing date.

III. The failure to file a petition (and petition fee) under the above options (I) or (II) within **TWO MONTHS** of the date of this Notice (37 CFR 1.181(f)) will be treated as a constructive acceptance by the applicant of the application as deposited in the USPTO. **THIS TWO MONTH PERIOD IS NOT EXTENDABLE UNDER 37 CFR 1.136(a) or (b).** In the absence of a timely filed petition in reply to this Notice, the application will maintain a filing date as of the date of deposit of the application papers in the USPTO, and original application papers (i.e., the original disclosure of the invention) will include only those application papers present in the USPTO on the date of deposit.

In the event that applicant elects not to take action pursuant to options (I) or (II) above (thereby constructively electing option (III)), amendment of the specification to renumber the pages consecutively and cancel incomplete sentences caused by any omitted page(s), and/or amendment of the specification to cancel all references to any omitted drawing(s), relabel the drawing figures to be numbered consecutively (if necessary), and correct the references in the specification to the drawing figures to correspond with any relabeled drawing figures, is required. A copy of the drawing figures showing the proposed changes in red ink should accompany with any drawing changes. Such amendment and/or correction to the drawing figures, if necessary, should be by way of preliminary amendment submitted prior to the first Office action to avoid delays in the prosecution of the application.

#### **Items Required To Avoid Processing Delays:**

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- Additional claim fees of **\$2154** as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

#### **SUMMARY OF FEES DUE:**

Total additional fee(s) required for this application is **\$3054** for a Large Entity

- **\$770** Statutory basic filing fee.
- **\$130** Late oath or declaration Surcharge.
- Total additional claim fee(s) for this application is **\$2154**
  - **\$810** for 45 total claims over 20 .
  - **\$1344** for 16 independent claims over 3 .

Replies should be mailed to: Mail Stop Missing Parts  
Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

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*A copy of this notice **MUST** be returned with the reply.*

*PL*  

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Customer Service Center

Initial Patent Examination Division (703) 308-1202

PART 1 - ATTORNEY/APPLICANT COPY

# EXHIBIT 5

PATENTS

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

*In re Application of* )  
Kossida *et al.* ) Prior Group Art Unit: 1652  
Serial No. 10/631,958 ) Prior Examiner: M. Monshipouri  
Filed: August 1, 2003 ) Atty. Dkt. No. 004974.00951

For: **REGULATION OF HUMAN CERAMIDE KINASE**

### **PETITION UNDER 37 C.F.R. § 1.182**

U.S. Patent and Trademark Office  
220 20th Street S.  
Customer Window, Mail Stop Petitions  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202

Sir:

Applicants request correction of the Updated Filing Receipt mailed June 21, 2004. The petition fee of \$130.00 under 37 C.F.R. §1.17(h) should be charged to our Deposit Account No. 19-0733. If any other fee is required or if this amount is incorrect, please charge or credit the account.

### **Relief Requested**

Applicants request that the U.S. Patent and Trademark Office issue a corrected filing receipt indicating a filing date of August 1, 2003.

### Reasons Relief Should be Granted

A corrected filing receipt indicating a filing date of August 1, 2003 should be issued because August 1, 2003 is the date on which the Applicants met the filing date requirements of 37 C.F.R. § 1.53(b).

### Facts In Support of Petition

1. Applicants filed this application as a continuation in part of Serial No. 09/696,896 on August 1, 2003. The application contained a specification as prescribed by 35 U.S.C. § 112, 65 claims, and eight sheets of drawings (Figs. 1-8). A copy of Applicants' stamped postcard receipt is attached as Exhibit 1. The postcard indicates that the U.S. Patent and Trademark Office's received the application, including the specification and claims, and Figures 1-8, on August 1, 2003. Thus, the requirements for a filing date under 37 C.F.R. § 1.53(b) were met on August 1, 2003.

2. On October 22, 2003 the U.S. Patent and Trademark Office mailed a Notice to File Missing Parts. The Notice correctly indicated a filing date of August 1, 2003. The Notice requested the statutory filing fee, the executed declaration, and the surcharge under 37 C.F.R. § 1.16(e). The Notice also asserted that Figures 1 and 2 were not present in the application as filed.

3. On December 19, 2003 Applicants filed a response with respect to the assertion that Figures 1 and 2 were not present in the application as filed. The response pointed out that the Figures were filed together with the application but that, even if these figures had not been included in the application as filed, the application incorporates parent application Serial No. 09/696,896 by reference in its entirety. See page 1 of the present application. The parent

application contains Figures 1 and 2.

4. On February 24, 2004 the U.S. Patent and Trademark Office mailed a second Notice to File Missing Parts. This Notice correctly indicated a filing date of August 1, 2003 and again requested an executed declaration.

5. Also on February 24, 2004 the U.S. Patent and Trademark Office mailed a filing receipt correctly indicating a filing date of August 1, 2003.

6. On March 22, 2004 Applicants responded to the Notices to File Missing Parts mailed October 22, 2003 and February 24, 2004 by providing the inventors' executed declaration and paying the required fees.

7. On June 21, 2004 the U.S. Patent and Trademark Office mailed an Updated Filing Receipt that incorrectly indicated a filing date of December 19, 2003.

8. On August 12, 2004 Applicants filed a Request for Corrected Filing Receipt and asked that the filing date on the Updated Filing Receipt be corrected to reflect the correct filing date of August 1, 2003.

9. On September 13, 2004 the U.S. Patent and Trademark Office mailed a response refusing to provide a Corrected Filing Receipt, asserting that "the filing date accorded to the application is the date the application met the filing date requirements of 37 C.F.R. § 1.53(b) or (c)." This is incorrect. December 19, 2003, however, is not the date the requirements of 37 C.F.R. § 1.53(b) were met; it is the date Applicants explained that Figures 1 and 2 were present in the application as filed by virtue of the application's incorporation by reference of the parent application.

Request for Refund

Because Applicants met the filing date requirements of 37 C.F.R. § 1.53(b) on August 1, 2003, Applicants respectfully requests a refund of the petition fee.

Respectfully submitted,

Date: September 17, 2004

By:



Lisa M. Hemmendinger  
Registration No. 42,653

Banner & Witcoff, Ltd.  
1001 G Street, N.W., Eleventh Floor  
Washington, D.C. 20001-4597  
(202) 824-3000

PATENT  DESIGN B&W Ref. 4974.951 Date 8/1/03  
 HAND CARRY Group/Section \_\_\_\_\_  
 Serial/Patent No. 1091614 + ENCINAS Bldg. L Attn/Soc. MH/MR Rm. 101  
 Inventor JOSE DAVID ENCINAS Client Bayer AG  
 Title IMPROVEMENT IN HUMAN CERAMIC DENTURE

The following has been received in the U.S. Patent and Trademark Office on the date stamped hereon:  
 Total no Spec. including # of Claims 10  Abstract  
 1 or more Independent claims 2  Formal  Informal  
 1 or less Drawing sheet(s) 8  Figs. 8  
 Declaration/Power of Attorney  Executed  Unexecuted  
 Assignment w/PTO Cover Sheet  
 IDS w/PTO 1449  References  w/Fee  
 Preliminary Amendment  
 Priority Claim (Foreign or U.S. Provisional) B&W # \_\_\_\_\_

Country Appl. # Date  
 & Foreign Priority Document(s)  
 Application 1091614 Continuation  Divisional   
 Parent Ser. No. 01/116111 Wt. 119345.544  
 U.S. Provisional \_\_\_\_\_ in Spec/Claims/Cover Sheet  
 Response to Missing Parts/Requirements did \_\_\_\_\_  
 Response to Notice to File Corrected Appl. Papers did \_\_\_\_\_  
 Request for Expedited Foreign Filing License  
 Request for Corrected  Filing Receipt  
 Response to Restriction/Election Requirement

Service Listing  Discrete  12 pages  
 Amendment  Response OA or  
 Petition for Extension of Time until \_\_\_\_\_  
 CPA  RCE  w/Ext. of Time - OA or  
 Request for Approval of Drawing Changes  
 Notice of Appeal & Fee  
 Oral  Appeal & Fee  Party  
 Request for Oral Hearing  
 Issue Fee  Advance Patent Copies (1 copy)  
 Notice of Allowance and  TRADEMARK  
 Amendment under 37 CFR 1.312  
 Request for Certificate of Correction  
 Transmittal  Fee Transmittal w/Amt. to Charge Deposit Acc.  
 Notice of Missing  
 S. O. \_\_\_\_\_ for \_\_\_\_\_  
 13

13  
 1091614-1 SEARCHED 1091614-1  
 Sequence drawing from 1091614-1  
 Also 1091614-1 application  
 w/ statement



UNITED STATES PATENT AND TRADEMARK OFFICE

REHS / hml

EXHIBIT 6

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

004974.00951

*SH/Car*

NOV 10 2004

BANNER & WITCOFF  
1001 G STREET N W  
SUITE 1100  
WASHINGTON, DC 20001

*noted*

COPY MAILED

NOV 08 2004

OFFICE OF PETITIONS

DECISION GRANTING PETITION

In re Application of  
Kossida, et al.  
Application No. 10/631,958  
Filed: August 1, 2003  
Attorney Docket No. 004974.00951

This is a decision on the petition filed September 17, 2004, to correct the application filed date from the currently accorded date of December 19, 2003, to August 1, 2003.

On August 1, 2003, the application was deposited.

On October 22, 2003, the Office of Initial Patent Examination mailed the Notice stating a filing date had been accorded the application, but that the oath or declaration and filing fee were missing. The Notice also indicated that Figures 1 and 2 as described in the specification appeared to have been omitted. With respect to the omitted figures, the Notice allowed a non-extendable period for reply of two months from its mailing date. On December 19, 2003, petitioner filed a response to the Notice and alleged the Figures 1 and 2 did accompany the original application papers, but, even if the figures were not located, the application was complete on filing because the application incorporated a prior application in its entirety, because drawings did not accompany the original disclosure. Obviously seeing only the omitted figures, the Office of Initial Patent Examination changed the filing date accorded the application from August 1, 2003, to December 19, 2003.

It has been determined that drawings are not, in fact, necessary to understand at least one claim within the meaning of the first sentence of 35 USC 113. It has been PTO practice to treat an application that contains at least one process or method claim as an application for which a drawing is not necessary for an understanding of the invention under 35 U.S.C. 113 (first sentence). A review of the record reveals that Claims 16, 18, 21, 24, 33, 38, 41, 57, 66, 73, and 74 are method claims. The present application is, therefore, deemed to be an application that does not require a drawing for an understanding of the invention. Accordingly, the application, as filed, was entitled to the filing date of August 1, 2003.

The application is being forwarded to the Office of Initial Patent Examination for further processing with a filing date of August 1, 2003. Prior to the first action on the merits, petitioner should file a preliminary amendment requesting entry of Figures 1 and 2. The Office of Initial Patent Examination will issue a corrected filing receipt.

*In re Application of Kossida, et al.*  
10/631,958

Page 2

Any inquiries related to this decision should be directed to the undersigned at (703) 305-0010.

*Kenya A. McLaughlin*

Kenya A. McLaughlin  
Petitions Attorney  
Office of Petitions

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